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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 121025585-3248-01]

RIN 0694-AF73

Amendment to the Export Administration Regulations: List of Items Classified Under Export Control Classification 0Y521 Series – Biosensor Systems

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Interim final rule with request for comments.

SUMMARY: In this interim final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to make certain items subject to the EAR and to impose on those items a license requirement for export and reexport to all destinations, except Canada. Specifically, this rule classifies specified biosensor systems, “software” and “technology” under Export Control Classification Numbers (ECCNs) 0A521, 0D521 and 0E521, respectively, on the Commerce Control List (CCL). As described in the final rule that established the 0Y521 series and that was published in the Federal Register on April 13, 2012 (77 FR 22191), items are added to the 0Y521 series upon a determination by the Department of Commerce, with the concurrence of the Departments of Defense and State, that the items should be controlled for export because the items provide at least a significant military or intelligence advantage to the United States or foreign policy reasons justify control. The items identified in this rule are controlled for regional stability (RS) Column 1 reasons. The only license exception available for these items is for official use by personnel and agencies of the U.S. Government.

**DATE:** This rule is effective [INSERT DATE OF PUBLICATION]. Comments must be received by [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION].

**ADDRESSES:** You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. The identification number for this rulemaking is BIS–2013–0007.
- By email directly to: [publiccomments@bis.doc.gov](mailto:publiccomments@bis.doc.gov). Include RIN 0694–AF73 in the subject line.
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230. Refer to RIN 0694–AF73.

**FOR FURTHER INFORMATION CONTACT:**

Elizabeth Sangine, Director, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance by phone at (202) 482-3343 or by email at [Elizabeth.Scottsangine@bis.doc.gov](mailto:Elizabeth.Scottsangine@bis.doc.gov)

**SUPPLEMENTARY INFORMATION:**

**Background**

BIS established the ECCN 0Y521 series to identify items that warrant control on the CCL but are not yet identified in an existing ECCN. Items are added to the ECCN 0Y521 series by the Department of Commerce, with the concurrence of the Departments of Defense and State, upon a determination that an item should be controlled because it provides at least a significant military or intelligence advantage to the United States or because foreign policy reasons justify such control. The ECCN 0Y521 series is a temporary holding classification equivalent to United States Munitions List (USML) Category XXI (Miscellaneous Articles) in part 121 of the International Traffic in Arms

Regulations, but with a limitation that while an item is temporarily classified under ECCN 0Y521, the U.S. Government works to adopt a control through the relevant multilateral regime(s), to determine an appropriate longer-term control over the item, or that the item does not warrant control on the CCL.

Items classified under ECCN 0Y521, including the items identified in this interim final rule as 0A521, 0D521 and 0E521 items, remain so-classified for one year from the date a final rule identifying the item is published in the *Federal Register* amending the EAR, unless the item is re-classified under a different ECCN, under an EAR99 designation, or the 0Y521 classification is extended. During this time, the U.S. Government determines whether it is appropriate to submit a proposed control to the applicable export control regime (e.g., the Australia Group) for potential multilateral control, with the understanding that multilateral controls are preferable when practical. An item's ECCN 0Y521 classification may be extended for two one-year periods to provide time for the U.S. Government and multilateral regime(s) to reach agreement on controls for the item, and provided that the U.S. Government has submitted a proposal to obtain multilateral controls over the item. Further extension beyond three years may occur only if the Under Secretary for Industry and Security makes a determination that such extension is in the national security or foreign policy interests of the United States. An extension or re-extension, including a determination by the Under Secretary for Industry and Security, will be published in the *Federal Register*.

#### *License Requirements, Policies and Exceptions*

The license requirements and policies for the ECCNs 0Y521 series appear in § 742.6(a)(7) of the EAR. ECCN 0Y521 items are subject to a nearly worldwide license requirement (i.e., for every country except Canada) with a case-by-case license review policy, through regional stability (RS Column 1) controls. The description and status of ECCN 0Y521 items appear in Supplement No. 5 to part 774 of the EAR, along with any

item-specific license exceptions, where applicable. Unless otherwise indicated, License Exception GOV is applicable to all ECCN 0Y521 series items, including those items identified in this notice, if the item is within the scope of § 740.11(b)(2)(ii) (Items for official use by personnel and agencies of the U.S. Government), as provided in § 740.2(a)(14). License Exception GOV is the only license exception that can be used for the items identified in this interim final rule.

*Addition of ECCN 0A521, 0D521 and 0E521 Items*

In this rule, BIS amends the EAR to make specified biosensor systems, and related “software,” and “technology” subject to the EAR and impose license requirements on these items. These items are being added to the 0Y521 series pursuant to a determination by the Department of Commerce, with the concurrence of the Departments of State and Defense, that these items should be controlled because they provide a significant military or intelligence advantage to the United States or because foreign policy reasons justify such controls. The specified biosensor systems, “software,” and “technology” are classified under ECCNs 0A521, 0D521 and 0E521, respectively. A brief description of each of these items and ECCNs follows.

ECCN 0A521 covers biosensor systems and dedicated detecting components capable of detecting certain aerosolized bioagents and having the following characteristics: capable of showing results in three minutes or less; containing an integrated bioaerosol collector and identifier; containing antibodies to the bioagents listed in the entry; and utilizing bioluminescence as a process. This entry also includes a *Related Controls* paragraph that differentiates ECCNs 1A004.c detection systems and 2B351 toxic gas monitoring systems and their dedicated detecting components controls on the CCL from 0A521 *Biosensor Systems*. That paragraph also refers exporters to USML Category XIV(f)(2) for equipment for the detection, identification, warning or monitoring of biological agents that is subject to the licensing jurisdiction of the

Department of State, Directorate of Defense Trade Controls. Finally, two Technical Notes are provided for this entry defining the term ‘dedicated’ and clarifying that the entry does not control biosensor systems that detect foodborne pathogens.

0D521 is “*Software*” for the function of biosensor systems controlled by ECCN 0A521.

0E521 is “*Technology*” for the “development” or “production” of biosensor systems controlled by ECCN 0A521.

The technical descriptions and the status of the specified items appear in the table found in Supplement No. 5 to part 774 of the EAR.

*License Applications for the New ECCN 0A521, 0D521 and 0E521 Items*

License applications for these items may be submitted through SNAP-R in accordance with § 748.6 of the EAR. Exporters are directed to include detailed descriptions and technical specifications with the license application, and identify the hardware as ECCN 0A521, the “software” as ECCN 0D521, and the “technology” as ECCN 0E521.

This rule is being issued in interim final form because while the Government believes that it is in the national security interests of the United States to immediately implement these controls, it also wants to provide the interested public with an opportunity to comment to the Government on the ultimate nature of export controls on these items.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as extended by the Notice of August 15, 2012, 77 FR 49699 (August 16,

2012), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

### **Rulemaking Requirements**

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor is subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid OMB control number. This rule affects two approved collections: (1) the Simplified Network Application Processing + System (control number 0694-0088), which carries a burden hour estimate of 43.8 minutes, including the time necessary to submit license applications, among other things, as well as miscellaneous and other recordkeeping activities that account for 12 minutes per submission; and (2) License Exceptions and Exclusions (0694-0137). With these initial 0Y521 series items, BIS does not believe that this rule will materially increase the number of submissions under these collections.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring prior notice, the opportunity for public comment and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States (*See* 5 U.S.C. 553(a)(1)). BIS, with the concurrence of the U.S. Departments of Defense and State, is implementing this rule because the items identified for the ECCN 0Y521 series in this rule provide a significant military or intelligence advantage to the United States. Immediate imposition of a license requirement is necessary to effect the national security and foreign policy goals of this rule. Immediate implementation will allow BIS to prevent exports of these items to users and for uses that pose a national security threat to the United States or its allies. If BIS delayed this rule to allow for prior notice and opportunity for public comment, the resulting delay in implementation would afford an opportunity for the export of these items to users and uses that pose such a national security threat, thereby undermining the purpose of the rule. In addition, if parties receive notice of the U.S. Government's intention to control these items under 0Y521 once a final rule was published, they might have an incentive to either accelerate orders of these items or attempt to have the items exported prior to the imposition of the control.

Further, BIS finds good cause to waive the 30-day delay in effectiveness under 5 USC 553(d)(3). Immediate implementation will allow BIS to prevent exports of these items to users and for uses that pose a national security threat to the United States or its allies. If BIS delayed this rule to allow for a 30-day delay in effectiveness, the resulting delay in implementation would afford an opportunity for the export of these items to

users and uses that pose such a national security threat, thereby undermining the purpose of the rule.

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Although notice and opportunity for comment are not required, BIS is issuing this rule as an interim final rule with a request for comments. All comments must be in writing and submitted via one or more of the methods listed under the ADDRESSES caption to this notice. All comments (including any personal identifiable information) will be available for public inspection and copying. Those wishing to comment anonymously may do so by submitting their comment via regulations.gov and leaving the fields for identifying information blank.

## **List of Subjects**

### *15 CFR Part 774*

Exports, Reporting and recordkeeping requirements.

Accordingly, part 774 of the Export Administration Regulations (15 CFR parts 730-774) is amended as follows:

## **PART 774 – [AMENDED]**

1. The authority citation for part 774 continues to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O.



13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2012, 77 FR 49699 (August 16, 2012).

2. Supplement No. 5 to Part 774 is revised to read as follows:

**SUPPLEMENT NO. 5 TO PART 774 - ITEMS CLASSIFIED UNDER ECCNS  
0A521, 0B521, 0C521, 0D521 AND 0E521**

The following table lists items subject to the EAR that are not listed elsewhere in the CCL, but which the Department of Commerce, with the concurrence of the Departments of Defense and State, has identified warrant control for export or reexport because the items provide at least a significant military or intelligence advantage to the United States or for foreign policy reasons.

<b>Item descriptor.</b> <i>Note: The description must match by model number or a broader descriptor that does not necessarily need to be company specific.</i>	<b>Date of initial or subsequent BIS classification.</b>  (ID = initial date; SD = subsequent date)	<b>Date when the item will be designated</b>  EAR99, unless reclassified in another ECCN or the 0Y521 classification is	<b>Item-specific license exception eligibility.</b>

		reissued.	
<b>0A521. Systems, Equipment and Components.</b>			
<p><i>No.1</i>  Biosensor systems and dedicated detecting components, i.e. cartridges and cells, capable of detecting all of the following aerosolized bioagents: anthrax, ricin, Botulinum toxin, Francisella tularensis, orthopoxvirus and Yersinia pestis, and having all of the following characteristics:</p> <ul style="list-style-type: none"> <li>a. Capable of showing results in three minutes or less;</li> <li>b. Has an integrated bioaerosol collector and identifier;</li> <li>c. Contains antibodies for any of the bioagents listed above; and</li> <li>d. Utilizes bioluminescence as a process.</li> </ul> <p><i>Related Controls(1)</i>See ECCN 1A004.c for detection systems and ECCN 2B351 for toxic gas monitoring systems and their dedicated detecting components, both of which are different from ECCN 0A521<i>Biosensor Systems.</i> (2) See 22 CFR Part 121, Category XIV (f) (2) for equipment for the detection, identification, warning or monitoring of biological agents that is subject to the</p>	<p>[INSERT DATE OF PUBLICATION] (ID)</p>	<p>March 28, 2014</p>	<p>License Exception GOV under § 740.11(b)(2)(ii) only.</p>

<p>export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.</p> <p>Technical Notes:</p> <p>1. For the purposes of this entry, the term dedicated means committed entirely to a single purpose or device.</p> <p>2. This entry does not control biosensor systems that detect food borne pathogens.</p>			
<b>0B521. Test, Inspection and Production Equipment.</b>			
[RESERVED]			
<b>0C521. Materials.</b>			
[RESERVED]			
<b>0D521. Software.</b>			
<i>No. 1</i> 0D521 “Software” for the function of Biosensor Systems controlled by ECCN 0A521.	[INSERT DATE OF PUBLICATION] (ID)	March 28, 2014	License Exception GOV under § 740.11(b)(2)(ii) only.
<b>0E521. Technology.</b>			
<i>No. 1</i> 0E521 “Technology” for the “development” or “production” of Biosensor Systems controlled by ECCN 0A521.	[INSERT DATE OF PUBLICATION] (ID)	March 28, 2014	License Exception GOV under § 740.11(b)(2)(ii) only.

DATED: March 21, 2013

Kevin J. Wolf

Assistant Secretary for Export Administration

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